AGENDA

‘Improving delays to diagnosis – when to suspect AS and PsA: Recognition and referral’- study day workshop

Friday11thOctober 2019
Copthorne Gatwick Hotel, Copthorne Way, Copthorne,
West Sussex, RH10 3PG

Time	Programme	Speaker
09.30	Arrivals / Welcome and Introduction	Trevor Weston - Principal KAM- Novartis Pharmaceuticals
09:45 -10:30	MSK?...Think AS/PsA. Recognition and referral.	Dr Carol McCrum- Consultant Physiotherapist, Eastbourne DGH
10.30 -11.30	Imagingconsiderations in suspected AS/PsA	Dr Carol McCrum
11:30-12:00	Question and Answer Session	Dr Carol McCrum
12.00 - 12.45	Lunch and networking	
12.45 - 1.15	Screening– history taking and clinical reasoning workshop	Dr Carol McCrum
1.15 – 2.15	Extra-articular manifestations – considerations and clinical assessments – practical workshop	Dr Carol McCrum
2.15- 2.30	Final questions and close of meeting	Dr Carol McCrum& Trevor Weston

This is a meeting for healthcare professionals only. If you would like to register your place at this meeting, please contact Trevor Weston - Novartis at: Trevor.weston@novartis.comor 07468 717363

PsA: Psoriatic Arthritis; AS: Ankylosing Spondylitis; MSK: musculoskeletal

NOVARTIS

Cosentyx secukinumab

This is a promotional meeting organised and funded by Novartis Pharmaceuticals UK Ltd.
Job code:COS19-R094a; Date of preparation: August 2019

Cosentyx▼ (secukinumab) Prescribing Information Please refer to the Summary of Product Characteristics before prescribing.
Indication: Cosentyx is indicated for: the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active psoriatic arthritis in adult patients, alone or in combination with methotrexate (MTX), when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Presentations: Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen.

Dosage & Method of Administration: *Psoriasis:* The recommended dose is 300 mg via subcutaneous injection. Dosing is given at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. If possible, areas of the skin that show psoriasis should be avoided as injection sites. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders (IR), the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. *Ankylosing Spondylitis:* The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks. Safety and efficacy in patients below the age of 18 years have not been established.

Contraindications: Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection.

Warnings & Precautions: *Infections:* Cosentyx has the potential to increase the risk of infections. Serious infections have been observed in patients receiving Cosentyx. Caution in patients with a chronic infection or a history of recurrent infection. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and Cosentyx should not be administered until the infection resolves. In clinical studies, most of these were mild or moderate upper respiratory tract infections such as nasopharyngitis and did not require treatment discontinuation. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Cosentyx should not be given to patients with active tuberculosis. Anti-tuberculosis therapy should be considered prior to initiation of Cosentyx in patients with latent tuberculosis. *Inflammatory bowel disease:* New cases or exacerbations of Crohn's disease and ulcerative colitis have been reported. Caution in patients with inflammatory bowel disease, including Crohn's disease and ulcerative colitis. Patients should be closely monitored. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If anaphylactic or other serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Live vaccines should not be given concurrently with Cosentyx. Patients receiving Cosentyx may receive concurrent inactivated or non-live vaccinations. *Latex-Sensitive Individuals:* The removable needle cap of the Cosentyx pre-filled syringe and the pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy -have not been evaluated.

Interactions: Live vaccines should not be given concomitantly with Cosentyx. In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP3A4 substrate). No interaction was seen when Cosentyx was administered concomitantly with methotrexate and/or corticosteroids in arthritis studies.

Fertility, pregnancy and lactation: *Women of childbearing potential:* Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. *Pregnancy:* It is preferable to avoid the use of Cosentyx in pregnancy, due to lack of adequate data. *Breast feeding:* Clinical decision on continuation of breast feeding during secukinumab treatment (and up to 20 weeks after discontinuation) in nursing mothers must be made, taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. It is not known if secukinumab is excreted in human breast milk. *Fertility:* The effect of secukinumab on human fertility has not been evaluated.

Adverse Reactions: *Very Common (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, rhinorrhoea, diarrhoea. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, neutropenia. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions. *Not known (cannot be estimated from available data):* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* In the placebo controlled period of clinical studies in plaque psoriasis, infections were reported. The majority of infections consisted of non-serious and mild to moderate upper respiratory tract infections, such as nasopharyngitis, which did not necessitate treatment discontinuation. There was an increase in mucosal or cutaneous candidiasis, but the cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients in both the Cosentyx and placebo groups. Over the entire treatment period (up to 52 weeks), infections were reported in 47.5% of patients treated with Cosentyx (0.9 per patient year of follow up). Serious infections were reported in 1.2% of patients treated with Cosentyx (0.015 per patient years of follow up). Infection rates observed in psoriatic arthritis and ankylosing spondylitis clinical studies were similar to those observed in the psoriasis studies. *Neutropenia:* Neutropenia was more frequently observed with secukinumab than with placebo, but most cases were mild, transient and reversible. The frequency of neutropenia in psoriatic arthritis and ankylosing spondylitis is similar to psoriasis. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions*: Urticaria and rare cases of anaphylactic reactions were observed. *Immunogenicity*: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing.

Legal Category: POM

MA Number & List Price: EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/003 - 150 mg pre-filled syringe x2 £1,218.78.

PI Last Revised: October 2018 (COS18-C277)

Full prescribing information, including a SmPC is available from: Novartis Pharmaceuticals UK Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR. Telephone: (01276) 692255 Fax: (01276) 692508**.**

Adverse Event Reporting:
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.comor online through the Patient Safety Information (PSI) tool at https://psi.novartis.com.

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com